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MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
POHNERT, STEVEN C	
ART UNIT	**PAPER NUMBER**
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,452	TABAKOFF ET AL.	
	Examiner	Art Unit	
	Steven C. Pohnert	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-12 and 26-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-12 and 26-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the action filed April 19, 2007. All arguments presented in the April 19, 2007 response have been thoroughly reviewed.

The objection to Figure 2 has been withdrawn as the figure has been amended to improve clarity.

Any rejections not specifically recited below have been withdrawn.

Claims 1, 6-12, 26-34 are pending.

This action is FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 6-12, 26-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims 1, 6-12, 26-34 encompasses a method of identifying individuals predisposed to "major depressive disorder" by detecting $[AACA]_7$ repeat polymorphism in "any" adenylyl cyclase type 7 (AC7) allele in a Caucasian female subject. Claim 2 is drawn to a "repeat polymorphism. The claims set forth the structural requirement "any" $[AACA]_7$ polymorphism of AC7 are

indicative of predisposition to major depressive disorders, although lacking guidance on a functional relationship of how any AC7 polymorphism is associated with major depressive disorders. Claims 33 and 34 are claims added by that amendment that further draw independent claims 1 and 26 to a nucleic acid fragment "corresponding" to nucleotides 5684 to 6062 of SEQ ID NO 1. As the specification does not set forth a specific definition for "corresponding" the reference to nucleotides 5684 to 6062 of SEQ ID No1 could be "any" nucleotides near SEQ ID NO 1, or any sequence that is somewhat complementary to SEQ ID NO 1 at the recited nucleotides.

When the claims are analyzed in light of the specification, the invention encompasses an enormous number of nucleotide molecules. The specification teaches adenylyl cyclase 7 (AC7) is a 6196 nucleotide cDNA comprising 73,020 nucleotides on chromosome 16 from bp 37,275,848 to 37,348, 868. The specification teaches, "'gene' encompasses both cDNA and genomic forms of a gene" (se page 7, lines 9 and 10). The specification further teaches the $[AACA]_7$ polymorphism of AC7 occurs in the 3'UTR and does list in table 2 repeat polymorphisms $[AACA]_5$ and $[AACA]_6$. The specification does not teach the location of the $[AACA]_7$ polymorphism in the 3'UTR. The specification does not teach any AC7 polymorphism, except $[AACA]_5$, $[AACA]_6$, and $[AACA]_7$. Although the specification lists $[AACA]_5$ and $[AACA]_6$ in table 2, it does not teach any phenotype associated with these polymorphisms. Further, the specification does not teach how the $[AACA]_{7\ genotype}$ or any other AC7 polymorphism alters AC7 function resulting in major depressive disorders. The specification further

teaches a subject is "any" human healthy or predisposed to major depressive disorders.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been disclosed. The instant specification teaches a sequence of AC7 is SEQ ID NO. 1. The specification further teaches a repeat polymorphism is a dinucleotide, trinucleotide, tetranucleotide or pentanucleotide repeat (see page 8, lines 28-29). The specification further teaches the $[AACA]_7$ repeat polymorphism of AC7 (AC7.R7) occurs in the 3'UTR, and lists in table 2 repeat polymorphisms $[AACA]_5$ and $[AACA]_6$. The specification does not teach the location of the $[AACA]_7$ polymorphism in the 3'UTR or if the location of $[AACA]_7$ polymorphism in the polymorphism is important in diagnosis. The specification further does not teach how the $[AACA]_7$ polymorphism alters the structure, function, or expression of AC7.

Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. other nucleotide sequences or positions with in a specific gene or nucleic acid), specific features and functional attributes that would distinguish different members of the claimed genus. The instant case the specification provides the $[AACA]_{7\ polymorphism}$ of the 3'UTR. The specification does not teach how the $[AACA]_7$ polymorphism or any other polymorphism of AC7 alters the structure, function or expression of AC7. The specification does not teach how altered function of AC7 or AC7 polymorphisms result in predisposition to major

depressive disorders. The specification does not teach how to identify any other AC7 polymorphisms. The claims read in light of the specification encompass any polymorphism of the 73 kb AC7 nucleic acid molecule. Each polymorphism would result in a distinctly different AC7 gene, as it would have a altered chemical composition and structure. This would encompass an enormous number of nucleic acid samples, as there 73,000 nucleotides in the AC7 genomic sequence.

In the instant application, the provided information regarding nucleic acid adenylyl cyclase 7 polymorphisms, do not constitute an adequate written description of the broad subject matter of the claims, and so one of skill in the art cannot envision the detailed chemical structure of the nucleic acids encompassed. Further the specification does not teach how AC7 polymorphisms result in a predisposition to major depressive disorders. Adequate written description requires more than a statement that nucleic acids with a particular quality are part of the invention and reference to a potential method for their identification. The nucleic acid sequence is required.

In conclusion, the limited information provided regarding adenylyl cyclase 7 polymorphisms is not deemed sufficient to reasonably convey to one skilled in the art nucleic acid molecules encompassed by the genus of "any" polymorphism or "any" repeat polymorphism in the adenylyl cyclase 7 gene.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

Response to Arguments

The response of April 9, 2007 on page 7, asserts," nucleotides 5684 to 6062 of the AC7 mRNA of GENBANK Accession No. NM 001114 set forth as SEQ ID NO 1 (Specification, page 44, lines 10-18). Applicants submit that the teaching of Example 5, in combination with the sequence listing clearly describes the location of the $[AACA]_7$ repeat polymorphism of interest in AC7 nucleic acids." This argument has been fully considered but is not found persuasive because the claims 1, 6-12, and 26-32 are not drawn to SEQ ID NO 1 or the recited GenBank accession, but "any" adenylyl cyclase type 7 allele with "any" $[AACA]_7$ repeat polymorphism in the 3' UTR. Adenylyl cyclase type 7 allele is not defined in the specification or claims and thus comprises a genus of nucleic acids. Further the recitation of the 3' UTR draws the claims to any nucleic acid 3' of the adenylyl cyclase type 7 start codon, including the rest of the chromosome on which it resides. Further "any" $[AACA]_7$ repeat can encompass AACA AACA AACA AACA AACA AACA AACA, or AACA that is present a total of 7 times in a sequence, without being consecutive. Finally, although claims 33 and 34 are drawn to nucleotides 5684 to 6062 of SEQ ID No 1, the use of corresponding language allows these limitations to broadly be interpreted as "any" nucleic acid sequence near 5684 to 6062 of SEQ ID No 1, and thus encompass an enormous genus of nucleic acids.

The response further asserts that the pending claims do not require the recited polymorphisms to have a direct impact on AC7, structure, function, and/or expression. Written description does require that the specification set forth a

representative number of species and/or a structure function relationship so that one of ordinary skill in the art could clearly envision the claimed invention. As the specification and claims teach only 1 species of the genus claimed by "any" adenylyl cyclase type 7 allele and "any" $[AACA]_7$ polymorphism, it does not teach a representative number of species. Further the response in the paragraph starting at the bottom of page 7 appears to suggest that no structural or functional characteristics are known for the instant polymorphism. Thus the skilled artisan would not use structure or function to envision other adenylyl cyclase type 7 allele [AACA] 7 repeat polymorphism that are capable of identifying Caucasian human females predisposed to major depressive disorders. The instant claims and specification thus lack adequate written description.

4. Claims 1, 6-12, 26-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying Caucasian females and Caucasian alcohol dependent females predisposed to "major depressive disorders" by detecting the presence of the $[AACA]_7$ polymorphism at nucleotide 5684 to 6062 of SEQ ID NO1, does not reasonably provide enablement for identifying "any" [AACA] 7 polymorphism in "any" adenylyl cyclase 7 (AC7). The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention there are many factors to be considered when determining whether there is sufficient evidence to support that a disclosure does not satisfy the enablement requirement and

whether any necessary experimentation is undue. These factors have been described by the court in re Wands, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in the Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and the breadth of the claims:

The claims encompass identifying human subjects predisposed to major depressive disorders by detecting the presence of "any" $[AACA]_7$ polymorphism in "any" AC7 polymorphism in Caucasian females. The claims 33 and 34 further draw the claims to "any" adenylyl cyclase type 7 allele comprising a nucleic acid comprising a fragment corresponding to nucleotides 5684 to 6062 of SEQ ID NO1.

The amount of direction or guidance and the Presence and absence of working examples in the specification.

The instant specification teaches a sequence of AC7 is SEQ ID NO. 1. The specification further teaches a repeat polymorphism is a dinucleotide, trinucleotide, tetranucleotide or pentanucleotide repeat (see page 8, lines 28-29). The specification further teaches the $[AACA]_7$ repeat polymorphism of AC7

(AC7.R7) occurs in the 3'UTR, and lists in table 2 repeat polymorphisms [AACA]$_5$ and [AACA]$_6$. The specification does not teach the location of the [AACA]$_7$ polymorphism in the 3'UTR or if the location of [AACA]$_7$ polymorphism in the polymorphism is important in diagnosis. The specification does not teach any AC7 polymorphism, except [AACA]$_5$, [AACA]$_6$, and [AACA]$_7$. The specification does not teach any other AC7 repeat polymorphism. The specification further does not teach how the [AACA]$_7$ polymorphism alters the structure, function, or expression of AC7. The specification does not teach how "any" AC7 polymorphism or AC7.R7 polymorphism functionally results in predisposition to major depressive disorders, such that a skilled artisan could form a predictive relationship between "any" AC7 polymorphism and major depressive disorders.

The specification further teaches a study of 746 Caucasian individuals (see page 20, line 18, and table1). The specification further asserts a statistically significant association between AC7.R7 allele and platelet forskolin stimulated adenylyl cyclase activity (see page 20 lines, 23-25 and table 3). The specification further asserts that the association between AC7.R7 and platelet forskolin stimulated adenylyl cyclase activity is not present in males (see page 23, lines 6-8, table 3 and 4), but not females (see table 5). The association between the platelet adenylyl cyclase activity, AC7.R7, and major depressive disorders is unclear.

The specification teaches in table 6 the AC7.R7 genotype and familial depression in 540 males (p=0.27) is a statistically significant association familial depression and familial depression in 206 females (p=0.008), 122 alcohol

dependent females (p=0.01). This statistically significant association familial depression with AC7.R7 in females appears significant enough to make the association between AC7.R7 and familial depression statistically significant upon combination of the male and female groups, although the relationship is not significant in the male group alone. The specification further teaches that when comparing females with familial depression to those with no family history results in a more statistically significant association with AC7.R7 in 133 females (p=0.005) and alcohol dependent females (p=0.002). Further there is statistically significant in relationship between AC7.R7 and familial depression compared to non-familial depression 79 females (p=0.01), but not 60 alcohol dependent females (p=0.06).

The specification does not teach how any polymorphism in AC7 alters AC7 expression, structure or function. The specification further does not teach a predictive relationship between any AC7 polymorphisms and major depressive disorders, except when $[AACA]_7$. The specification does not teach how "any" AC7.R7 polymorphism functionally results in predisposition to major depressive disorders, such that a skilled artisan could form a predictive relationship between ""any" AC7.R7 polymorphism and major depressive disorders.

The state of prior art and the predictability or unpredictability of the art:

The art teaches genetic variations and associations are often irreproducible. Hirschhorn et al. (Genetics in Medicine. Vol. 4, No. 2, pages 45-61, March 2002) teaches that most reported associations are not robust. Of the 166 associations studied three or more times, only 6 have been consistently

replicated (see abstract). Hirschhorn *et al.* suggest a number of reasons for the irreproducibility of studies, suggesting population stratification, linkage disequilibrium, gene-gene or gene-environment interactions, and weak genetic effects and lack of power are possible factors that lead to such irreproducibility. Hirschhorn *et al.* caution that the current irreproducibility of most association studies should raise a cautionary alarm when considering their use as diagnostics and prognostics (p. 60, Col. 2). Thus, Hirschhorn cautions in drawing conclusions from a single report of an association between a genetic variant and disease susceptibility.

Additionally, Ioannidis (Nature Genetics, 2001, Vol. 29, pages 306-309,) teaches that the results of the first study correlate only modestly with subsequent research on the same association (abstract). Ioannidis teaches that both bias and genuine population diversity might explain why early association studies tend to overestimate the disease protection or predisposition conferred by a genetic polymorphism (abstract).

Post-filing art reveals that most gene association studies are typically wrong. Lucentini (The Scientist, 2004, page 20) teaches that it is strikingly common for follow-up studies to find gene-disease associations wrong (left column, 3rd paragraph). Lucentini teaches that two recent studies found that typically when a finding is first published linking a given gene to a disease there is only roughly a one-third chance that the study will reliably confirm the finding (left column, 3rd paragraph). Lucentini teaches that bigger sample sizes and more family-based studies, along with revising statistical methods, should be included in the gene association studies (middle column, 1st complete paragraph).

Further Stephens et al (Science, 2001, volume 293, pages 489-493)

teaches SNPs are expressed variably across populations (See abstract). Accordingly, the teachings of the specification regarding a Caucasian population would not provide the skilled artisan with a predictable correlation that the allele, AC7.R7, let alone "any" AC7 allele, would be associated with a major depressive disorder in any population.

As the art teaches association of a polymorphisms are expressed variably across populations, the skilled artisan would be unable to predictably associate "any" AC7 mutation with major depressive disorders in "any" human population. Although there is a statistical association between AC7.R7 and major depressive disorders in Caucasian women, this can not be broadly interpreted to all women because the art teaches polymorphisms are expressed differently across ethnic populations.

The level of skill in the art:

The level of skill in the art is deemed to be high.

Quantity of experimentation necessary:

In order to practice the invention as claimed, one would first have to establish that a predicative relationship exists between "any" [AACA] 7 repeat polymorphism in AC7 polymorphism and a major depressive disorder in Caucasian females. The specification teaches a [AACA] 7 repeat polymorphism is statistically associated with predisposition to major depressive disorders in Caucasian females, and alcohol dependent Caucasian females, however the specification is not enabling for "any" $[AACA]_7$ polymorphism. . The specification does not teach how "any" AC7.R7 polymorphism or AC7.R7

polymorphism functionally results in predisposition to major depressive disorders, such that a skilled artisan could form a predictive relationship between "any" AC7.R7 polymorphism and major depressive disorders.

The use of corresponding language in claims 34 and 35 would further require undue and unpredictable trial and error experimentation, as the claims are broadly drawn to "any" nucleic at or near the recited positions. The skilled artisan would thus have to determine the nucleic acids encompassed by the claims. The specification does not provide sufficient guidance as to how to detect additional $[AACA]_7$ repeat polymorphism or other genes which can be used to determine whether a Caucasian female is predisposed to a major depressive disorder. Extensive experimentation would be required to identify additional $[AACA]_7$ repeat polymorphism associated with major depressive disorders, polymorphisms linked to AC7.R7, and alleles that can serve as a substitute for AC7.R7. For example, such experimentation may involve sequencing the genome of a Caucasian female who has a major depressive disorder or in any other sequence of chromosome 8 of that subject to obtain a first haplotype, sequencing the genome of Caucasian subjects not predisposed to major depressive disorders, comparing the results of this sequencing analysis in order to try to identify additional polymorphisms present in the genomes of subjects predisposed to major depressive disorders and which are absent in the genomes of subjects that do not predisposed to depressive orders. Additional experimentation might also involve performing the above method in a

representative number of non-human organisms or in a representative number of Caucasian females.

While methods for identifying haplotypes are known in the art, such methods provide only the general guidelines that allow researchers to randomly search for mutations that may linked to a particular phenotype. The results of performing such methodology are highly unpredictable. The specification has provided only an invitation to experiment. The specification does not provide a predictable means for identifying linked or substitute haplotypes or $[AACA]_7$ repeat polymorphisms of AC7.

Experimentation would be replete with unpredictable trial and error analysis because the specification teaches, " "any" $[AACA]_7$ repeat polymorphism in AC7 polymorphism is both associated with major depressive disorders in Caucasian females and alcohol dependent females. One of skill in the art would thus have to determine if "any" $[AACA]_7$ repeat polymorphism in AC7 is statistically associated with major depressive disorders as in Caucasian women. This would require undue trial error experimentation to determine if a statistical association of "any" $[AACA]_7$ repeat polymorphism present and statistically associated with major depressive disorders.

Due to the scope of the claims, one of skill in the art would be required to further undertake extensive trial and error experimentation to determine if $[AACA]_7$ repeat polymorphism is associated with the predisposition to major depressive disorders in Caucasian females.

Therefore, in light of the breadth of the claims, the lack of guidance in the specification, the high level of unpredictability in the associated art, the nature of the invention, the negative teachings in the art, and the quantity of unpredictable experimentation necessary to practice the claimed invention, it would require undue experimentation to practice the invention as claimed.

Response to arguments

The response of April 19, 2007 asserts on page 8, that the amended claims are enabled. This argument has been fully considered but is not found persuasive, because the claims and specification do not adequately describe "any" AC7 gene or "any" adenylyl cyclase type 7 in such a way that one of skill in the art would be able to make and use the instant invention. As stated previously, the skilled artisan would have to determine what "any" AC7 gene broadly encompasses and "any" $[AACA]_7$ repeat polymorphism. Further "any" $[AACA]_7$ repeat can encompass AACA AACA AACA AACA AACA AACA AACA, or AACA that is present a total of 7 times in a sequence, without being consecutive. This would be unpredictable as the specification suggests the use of an accession number or SEQ ID NO 1, but does not define AC7 as either, the claims thus broadly read on "any" human gene that can be referred to as adenylyl cyclase type 7 allele. Further, the specification references AC7 by a GenBank accession number, which is changed as error or mutations are identified and thus is not static. Further the reference to a gene by adenylyl cyclase type 7 broadly encompasses the genomic sequence including introns, exons, promoter and enhancer regions, as well as splice variants. Finally, claims

33 and 34 draw the claims to a specific SEQ ID NO, but use corresponding language which suggests the claims are not limited to the nucleotide and sequence recited. The skilled artisan would thus have to repeat the experiments to determine which nucleotides are encompassed and if a correlation can be made with the sequences found and major depression. As the skilled artisan could not clearly envision the nucleic acid sequences encompassed by the claims, the artisan would be enabled to make and use the instant invention.

The enablement rejection is thus maintained.

New Grounds of Rejection Necessitated by amendment

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 6-12, 26-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6-12, 26-34 are indefinite as they recite an $[AACA]_7$ repeat polymorphism. It is unclear what is encompassed by an $[AACA]_7$ polymorphism. Is the sequence AACA AACA AACA AACA AACA AACA AACA or AACA that is present a total of 7 times in a sequence, without being consecutive.

Claim 33 and 34 are indefinite over the recitation of "corresponds to nucleotides 5684 to 6062." Corresponding is not an art recognized term to describe the relationship between two nucleic acid sequences. It is not clear as to whether a corresponding nucleotide refers to nucleotide which is at the same position as position 16 in the sequence of SEQ ID NO: 1 or to a nucleotide which

is at a nearby position (e.g., position 5484 or 6063 etc). It is also unclear as to whether a corresponding nucleotide refers to a similar nucleotide (e.g., an A) or to the same nucleotide at any position in SEQ ID NO: 1 or in any sequence related to or unrelated to SEQ ID NO: 1 (i.e., if this recitation serves only to define the nucleotide as a T, and does not define the flanking nucleotides). Because the term "corresponds" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to nucleic acid sequences, one of skill in the art cannot determine the meets and bounds of the claimed subject matter.

Summary

No claims are allowed.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

/Carla Myers/
Primary Examiner, Art Unit 1634